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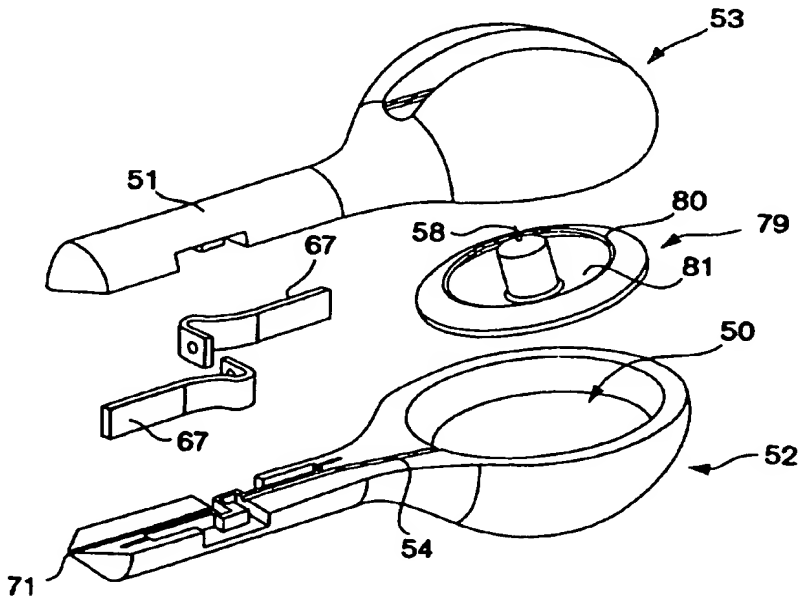
(54) Title: GUIDEWIRE STORED ON A ROTABLE REEL GUIDEWIRE SYSTEM

(57) Abstract

A method and apparatus are provided for releasably storing the additional exchange length of a medical guidewire within a housing, in a compacted configuration until it is needed by the physician to perform a catheter exchange. This guidewire has a distal portion which is similar to a traditional guidewire in length and construction and is used throughout the catheterization procedure much like a conventioanl guidewire. A proximal portion of the guidewire provides added length to effect a catheter exchange in the manner of a conventional exchange wire but may be tightly compacted and stored out of the way within a storage receptacle until the moment that the added length is needed for an exchange. The storage receptacle enables the physician to utilize the distal portion of the guidewire wire much like a conventional guidewire, then release the proximal portion quickly to effect a catheter exchange. The readily available additional length of wire offers the physician all the advantages of a traditional exchange wire while avoiding the handling problems associated with an uncontained exchange length that is unneeded during much of the procedure. The guidewire wire containment system of the present invention simplifies catheterization procedures by enabling the physician to maintain wire position during an exchange while keeping the exchange length of wire conveniently contained until it is needed to complete the procedure.



GUIDEWIRE STORED ON A ROTABLE REEL GUIDEWIRE SYSTEM

Field of the Invention

This invention relates to medical guidewires, extension wires and exchange wires and to improved methods and devices to facilitate procedures involving their use.

Background of the Invention

A wide variety of medical catheterization procedures involve the cooperative use of a guidewire over which the catheter can be threaded so that the guidewire can guide the catheter to the intended site in the patient's body. The use of a guidewire reduces the risk of trauma to the patient by the advancing catheter and enables the catheter to be advanced quickly, thereby reducing the time required for the procedure. The guidewire typically is more easily manipulated by the physician into a desired position in the patient's body than is the far more flexible catheter. After the guidewire has been directed to the desired location in the body, the catheter then can be threaded over and along the guidewire, with the wire providing support and guidance for the flexible catheter.

Guidewires are used frequently in connection with catheters adapted for the diagnosis or treatment of the cardiovascular system. They are useful particularly in connection with those procedures where it may be necessary for the physician to use a series of different catheters that are inserted into and withdrawn from the patient. Each of the catheters may be provided with a different shape, size, configuration or implement suited for a specific purpose. For example, angiographic studies typically include the use of at least three cardiac catheters including a right coronary artery catheter, a left coronary artery catheter and a pigtail catheter. Each has a different shape and configuration at its distal end (the end inserted into the patient; the opposite end, is the "proximal" end), each

Dilatation catheters commonly used in PTCA include an elongate flexible shaft of the order of about 150 cm long having a dilatation balloon mounted to the distal end of the shaft and an inflation lumen extending longitudinally within the shaft from the proximal end to the interior of the balloon so that the balloon may be inflated and deflated. Often such PTCA catheters also are provided with a full length guidewire lumen that receives a guidewire and terminates in openings at the distal tip of the shaft and at the proximal end of the catheter. When the guidewire and catheter are placed within a patient's artery, the guidewire can be manipulated and navigated to a desired location. The catheter then can be advanced, guided by the guidewire, to that location.

Typically, the balloon dilatation catheter and guidewire are guided to the entrance of one of the coronary arteries through another previously placed, larger diameter, single lumen catheter (a guide catheter). The guide catheter commonly is percutaneously inserted into the patient's femoral artery and is advanced along the aorta toward the heart. The guide catheter typically is provided with a pre-shaped distal tip adapted to engage and remain at the coronary ostium leading to the coronary artery. Once positioned, the guide catheter remains in place throughout the procedure to provide direct, quick access to the entrance of the coronary artery.

It is common during a PTCA procedure for the physician to exchange the balloon catheter for another catheter. This may occur if the physician initially performed a partial dilatation with a small diameter balloon and then wished to further dilate the patient's artery by using a catheter having a larger balloon. Catheters may also be exchanged to perform further operations in the artery such as stent placement or other treatment. Several techniques are commonly used to exchange a catheter, all designed to enable withdrawal of the catheter without losing guidewire position.

Another technique omits the necessity for an exchange wire by providing a guidewire extension that is attached to the proximal end of the conventional length indwelling guidewire, thereby effectively extending the length of the portion of the guidewire that protrudes out of the patient. The guidewire length is extended sufficiently to permit the catheter to be withdrawn and a new catheter to be threaded back into the patient without losing guidewire position. U.S. Patent 4,917,103 discloses an illustrative guidewire extension system.

It would be desirable to provide a simple, effective and inexpensive system and technique for providing an extended length guidewire to enable withdrawal of an indwelling over-the-wire catheter while leaving the guidewire in place and to provide a system to facilitate catheter exchanges. It is the general object of the present invention to provide such a system.

Summary of the Invention

The present invention provides an improved method and apparatus for performing a catheter exchange using a guidewire. This invention enables a physician to carry out a catheter exchange while maintaining guidewire position within the patient. The guidewire of the present invention has a distal guidewire portion of approximately 145 centimeters in length and a flexible proximal extension portion of approximately 155 centimeters in length, yet avoids the handling difficulties usually associated with a 300 centimeter length exchange wire. The long guidewire of the present invention is more manageable because the proximal extension portion, that provides the additional length needed for an exchange, may be gathered up and retained in a compact form capable of being held within the hand of the user until it is needed for an exchange. Though the added length of conventional exchange wires can be cumbersome to handle, the

away from the compacted proximal portion of the wire. This type of housing is intended for one-time use. The shell may be molded or heat sealed around the compacted extension portion during manufacture. The shell may be removable by a pull tab or a snap, tearing away completely from the extension portion of the wire. Upon release from the housing, the proximal portion of the wire assumes its straight configuration, in readiness for a catheter exchange. Once used, the split shell is spent and cannot be reused to recoil and store the wire. To facilitate use after the exchange, the physician may disconnect the extension portion from the indwelling guidewire portion of the wire if the connection is releasable. If the connection is permanent, the physician may wish to cut off the proximal portion or simply leave the full length intact for the remainder of the procedure.

Before the housing is removed it may serve as a steering handle for the distal guidewire portion. The coil of wire provides a handle through which torque may be transmitted to the straight distal portion of the wire. The size and shape of the shell housing surrounding the coil are suitable to enable it to be gripped and manipulated as needed to maneuver the wire through the patient's vasculature.

Not infrequently during a catheterization procedure, multiple exchanges are contemplated. To accommodate the possibility of multiple exchanges, several embodiments of the housing may be reused to recapture the proximal extension portion of the wire after a first exchange and store it in readiness for future exchanges. One embodiment of this type of housing has a hollow proximal storage portion having interior surfaces shaped to receive and direct the wire into a coil. The formed coil may lie approximately in a plane that is generally perpendicular to the axis of the straight wire portion. The proximal storage end of the housing transitions into a neck shaped to guide the wire out of the housing as it uncoils. The coil of wire retained within the housing may

rotate freely about an axle to quickly unwind a stored wire. The spool may have catch members around its perimeter surface to prevent the wire from springing off the spool once it has been wound.

It is among the general objects of this invention to provide an improved guidewire storage system and method that will facilitate an over-the-wire catheter exchange while maintaining wire position within the patient.

It is another object of the invention to provide a guidewire having a distal guidewire portion and a proximal extension portion that is more resilient and flexible than the distal portion such that it may be stored in a compact configuration within a small receptacle without adverse permanent deformation.

A further object of the invention is to provide a receptacle that is an easily removable shell housing to retain the compacted portion of the guidewire.

Still another object of the invention is to provide a housing that enables the user to return the proximal extension portion of the guidewire to its compacted form within the housing after having been extended to perform a catheter exchange.

Still a further object of the invention is to provide a method of catheter exchange using the type of guidewire described where the proximal portion of the wire remains stored in a compacted form within a housing until it is ready to be used by the physician for an exchange.

Another object of the invention is to provide devices and techniques of the type described that are inexpensive and simple to make and use.

FIG. 7 is a side view of the shell housing containing a coil of wire in a plane which is parallel to the axis of the extending distal portion of the guidewire.

FIG. 7A is a sectional view of the shell housing containing the coil of wire around a lightweight spool in a plane which is parallel to the axis of the extending distal portion of the guidewire shown in FIG. 7 along the line 7A-7A.

FIG. 8 is an illustration of the outside of a reusable housing capable of recapturing the extension portion of the wire.

FIG. 9 is a longitudinal sectional illustration of the proximal extension portion of the guidewire disposed within the reusable housing.

FIG. 10 is a sectional illustration of the reusable housing having a shortened neck.

FIG. 11 is a sectional illustration of the proximal portion of a modified form of the housing having an interiorly convex bottom wall.

FIG. 12 is a sectional illustration of an embodiment of the reusable housing having a storage portion that is rotatable relative to the neck.

FIG. 12A is sectional illustration of the reusable housing having a storage portion that is rotatable relative to the neck shown in FIG. 12 along the line 12A-12A.

FIG. 13 is a side view of a housing that stores the wire on a wire storage reel that is rotated by an automatic return spring.

FIG. 14 is a sectional view of the housing of FIG. 13 along the line 14-14

FIG. 15 is an exploded view of the housing depicting the wire storage reel, return spring, release lever, and wire brake system.

FIG. 15A is a side view of a cantilever spring used in the wire brake system.

FIG. 15B is a front view of a cantilever spring used in the wire brake system.

FIG. 15C is an illustration of the constant torque automatic return spring.

FIG. 15D is a side view of the storage reel having projections to locate the wire.

FIG. 18 is an illustration of a housing having a free-wheeling wire storage reel.

FIG. 18A is an exploded view of a housing having a free-wheeling wire storage reel.

FIG. 18B is a side view of the free-wheeling wire storage reel containing the wire under a projecting lip.

FIG. 18C is a side view of the free-wheeling wire storage reel containing the wire under a projecting lip.

FIG. 19 is an isometric view of an open wire receptacle comprising a spool and a tab for grasping.

FIG. 19A is a side view of the open wire receptacle comprising a spool and a tab for grasping.

FIG. 19B is a front view of the open wire receptacle comprising a spool and a tab for grasping.

FIG. 19C is a detail of the U-shaped channel of the spool having circumferential shoulders to hold the restraining wrap.

FIG. 19 D is a detail of the U-shaped channel of the spool having wire catches formed to pinch and hold the ends of the wire.

Description of the Illustrative Embodiments

FIG. 1 illustrates, in highly diagrammatic form, a catheter 1 and guidewire 3 which have been inserted into a patient's femoral artery and have been advanced to the region of the patient's heart 5 where a desired procedure will be performed. The guidewire 3 and catheter 1 will have been inserted and placed in the artery in accordance with well known procedures typically including the preliminary placement of a single lumen guide catheter (not shown in FIG. 1).

shaft 11 may be formed from a variety of conventional polymers used to form catheter shafts such as polyethylene and nylon, among others. The catheter shaft 11 may be of any conventional construction such as, for example, an extruded two lumen shaft (FIG. 2A) or a pair of coaxial tubes 6, 8 (FIG. 2B) in which the inner tube defines the guidewire lumen 2. The material from which the catheter shaft is formed and which defines the guidewire lumen, should have sufficiently low frictional characteristics so as to cooperate with the guidewire to enable the catheter shaft to easily slide over the guidewire. The outer surface of the guidewire 3 may be coated with a material to enhance its lubricity, such as Teflon, hydrophilic material or other materials commonly used for such purpose.

The proximal end of the catheter includes a bifurcate fitting 14 which joins a guidewire leg 15 and an inflation leg 16 to the catheter shaft 11 to communicate, respectively, with the guidewire and inflation lumens 2, 4. The inflation leg 16 has a fitting 17 at its proximal end that may be connected to a source of pressurized inflation medium. A similar connector fitting may be attached to the proximal end of the guidewire leg 15.

The operation and function of a conventional over-the-wire catheter and guidewire is well known to those familiar with the art. Should it be desired to effect a catheter exchange, one common approach is to use an extension wire that can be attached to the proximal end of the guidewire so that the combined overall length of the guidewire and extension wire (not shown) may be of the order of 300 cm long. The additional effective length, as compared to the conventional guidewire length is represented by the phantom line 18 in FIG. 1. The length of the extended guidewire is such that its proximal end 10 is spaced from the proximal end of the guide catheter by a distance that is greater than the length of the operating (dilatation) catheter. Consequently, a portion of the guidewire or extension always is exposed and can be grasped by the physician to maintain the position

long as a proximal portion 21 of the guidewire is made of a more elastic material that avoids adverse permanent deformation. As described in further detail below, the proximal extension portion 21 should be capable of returning to a substantially undeformed, straight, configuration after being constrained in a tightly gathered configuration such as the coil shown in FIG 4.

The proximal extension portion 21 of the guidewire 22, having the desired elastic properties, may be formed from material having a lower modulus of elasticity than the distal portion of the wire. The wire should be capable of returning to a straight configuration after release from storage to enable the over-the-wire catheter to be exchanged. A suitable material for the wire is considered to be the superelastic form of nitinol, a titanium-nickel alloy which has a modulus of elasticity of the order of 8,000,000 p.s.i., as compared to about 29,000,000 p.s.i. for stainless steel. Nitinol wire can be coiled tightly for storage yet return to an undeformed, straight configuration immediately upon release. A range of other materials also may be suitable for the proximal extension portion as long as they result in no permanent deformation and allow for manual loading of the wire into a storage housing. Other possibilities include: thin wires of material other than nitinol, arranged in a braid or close pitched spring having an inner core wire; plastic jacketed single filament wire; stiff plastic; or reinforced plastic.

One embodiment of a receptacle to retain the proximal extension portion of the wire in a compact configuration is a housing illustrated in FIGS. 5, 6, 7 and 7A. The housing may comprise a shell 23 that contains the proximal extension portion of the wire 21 in its coiled configuration until it is needed to complete an exchange procedure. The shell 23 may be formed around the coil by heat shrink wrapping plastic material around the coil. During shrink wrapping, the wire may be restrained in its coiled form around a light weight spool 28 or it may be held together by convenient temporary restraining

32 may be somewhat conical, having a sidewall 38 that diverges from a neck 35 to a bottom wall 36 of the housing. The bottom wall 36 may be attached to the housing by ultrasonic welding or by an adhesive bond.

After an exchange, the wire may be recoiled by reinserting the proximal portion of the wire 21 into the access port 45 and advancing the wire into the housing 30. The wire passes through the bore 33 of the neck 35 and enters the housing 30 where it encounters the bottom wall 36, buckles, then springs outward radially in a coiled shape. As the insertion continues, the divergent sidewall 38 guides the wire to the inside corners 37 of the storage portion 31 of the housing 30 where the wire is contained in a coil.

The bottom wall 36 may be about one inch in diameter. The divergent sidewall may taper to a diameter of approximately 0.300" at the neck 35. These dimensions are intended to be illustrative only and the housing may be any size found to be preferred by the user, bearing in mind practical limitations. Housings larger than three inches in diameter may be too bulky to hold comfortably in one hand and housings smaller than 0.250" coil the wire so tightly that the increased reaction force, created by the wire's resiliency, makes the wire more difficult to load and unload.

The neck 35 of the housing is shaped to guide straightened wire to and from the interior of the housing 30 where the wire resides in a coiled configuration. During withdrawal, the wire uncoils within the cone area and then becomes essentially straight as it passes through the access port 45 and leaves the housing. The friction present between the wire 21 and the bore 33 of the neck 35 prevents the wire from suddenly springing out of the storage portion 31. The neck 35 may be elongated as shown in FIG. 9 or quite short in comparison to the length of the cone portion as is shown in FIG. 10. The neck 35 may have an outside diameter on the order of 0.300". A bore 33 through the neck is dimensioned to slidably receive the guidewire. A clamp 34 may be employed on the neck

the wire, torque may be applied in only one direction to avoid disconnecting a hypotube connector of the type disclosed in U.S. Patent No. 5,133,364 (Palermo et al.). Such connectors engage when the extension wire is rotated in one direction and disengage when rotated in the opposite direction. The proximal end of the distal guidewire portion 20 of the wire should not be inserted deeply into the housing 30 as it may be permanently deformed if it is coiled within the storage portion 31 of the housing.

FIG. 11 shows the conical housing 30 having an interiorly convex shaped bottom 40 which serves to help direct the proximal extension portion of an entering wire 21 to the inside corners 37 of the cone for proper coiling. As the wire enters the storage region 31, it will first encounter the apex 41 of the end cap which deflects the wire radially outward toward the corner 37 of the housing. As the wire is inserted into the housing, it will continue to be guided into a coil at the inside corners 37.

FIGS. 12 and 12A shows a modified embodiment of the housing in which the storage portion 31 is rotatable with respect to the neck 35. Enabling such relative rotation may reduce the risk of the wire becoming twisted as it uncoils and exits the housing. The storage portion 31 and neck 35 may be rotatably joined by the interlocking connection of an outwardly projecting lip 43 on the storage portion with an inwardly projecting shoulder 44 on the neck. In this embodiment a guide tube 42 may be provided to receive the proximal end of an entering wire in the neck of the housing and guide it, as it advances, to the storage portion 31. The guide tube prevents the wire from becoming caught on the lip 43 and shoulder 44 connection, guiding it instead along the divergent sidewall 38 of the storage portion so that it may become coiled along inside corners 37 of the cone. The guide tube 42 is attached to the interior surface 32 of the storage portion 31 and extends into the bore 33 of the neck 35. The distal end of the guide tube 42 is flared open to a diameter that is approximately equal to that of the bore 33 of the neck 35 to

return spring 55 is shown in FIGS. 14, 15, 15C and 16 and is available from the Vulcan Spring Mfg. Co. of Telford, PA. It is a constant torque type made from a strip of thin rolled steel traveling between two spools. The spring is coiled upon itself into a storage spool 61 at one end, and at the other end, is wound reverse to its natural curvature into an output spool 60. When released, torque is obtained from the output spool 60 as the spring 55 returns to its natural curvature on the storage spool 61. The hub 56 of the storage reel 49 shown in FIGS. 13 and 14 is serves as an output spool so that as the reel rotates to uncoil the wire, the return spring spools onto the hub. When it is desired to recoil the wire by reversing the direction of rotation of the storage reel 49, the stored torque energy present in the output spool 60 which has been coiled onto the hub 56 of the reel will provide torque to rotate the reel until the spring becomes completely recoiled on the storage spool 61. The spring wound upon itself forming the storage spool 61 will be retained in a spring retainer recess 62 which is formed within the housing 48 adjacent to the wire storage reel 49. The constant torque provided by this spring throughout its travel between the spools creates a steady, moderate wire return speed into the housing. To avoid coiling and permanent deformation of the distal guidewire portion 20 of the wire, it is desirable to stop the wire's progress onto the return reel just before the hypotube connection 25 enters the housing. The reel can be made to stop at this predetermined point by designing the length of the return spring 55 to rotate the reel the correct amount of revolutions so that only the proximal extension portion 21 of the guidewire becomes coiled.

Automatic return of the wire onto the storage reel may be stopped by a release lever 59 that is pivotally mounted between its ends to the housing and engages the reel, holding it from rotating. The release lever has a handle end 64 that is operated by the user and a pawl end 65 which protrudes through the body of the housing and engages

maneuvered through the patient's vessels.

As shown in FIG. 14, the bore 54 of the neck 51 may be oriented to guide the wire to and from the perimeter of the reel 49 to facilitate engagement with the wire securing means on the storage reel. As shown in detail in FIGS. 15D and 15E the wire may be held onto the reel by several wedge shaped fingers 75 that project from the side of the reel 49, pointing radially outward around its perimeter. The wedge shape of the fingers causes the wire to become pinched between the converging surfaces of the side of the wedge and the sidewall of the reel, frictionally engaging it to prevent slippage. As reel rotates in the "coil" direction, the proximal end of the wire 21 projecting into the storage area 50 of the housing becomes trapped between the inside edge of the wedge shaped finger 75 and the surface of the reel. As the reel continues to rotate, wire will be continually drawn into the housing and snared on to succeeding projections 75 of the reel. As shown in FIG 13, the plane of rotation of the reel may be angled slightly away from the axis of the incoming wire to ensure that the entering wire 21 contacts the side of the reel having projections.

FIGS. 16, 16A and 16B show another embodiment of a spring driven device. In this embodiment, instead of a friction brake, the release lever 83 (not shown in FIG. 16) is itself constructed to regulate movement of the wire into or out of the housing. FIG. 16A shows the release lever 83 which is pivotally mounted, at its center 88, between the housing halves 52 and 53 (not shown). The lever 83, as shown in FIG. 16C, has pawls 84 and 85 at each end for engagement with square teeth 90 of the storage reel 78. The pawls are located at the ends of flexible arms 77 extending from the release lever 83. Each of the uncoil pawl 85 and the coil pawl 84 has an angled surface 86, that allows the square teeth 90 of the rotating reel 78 to slip by the pawl, and a flat edge surface 87 that engages the square teeth, stopping rotation of the reel. The bottom side of the release lever of FIG. 16C is shown in FIG. 16D. As shown in FIG. 16D the angled surface of each pawl

by the locking interface of the square teeth 90 with the flat edge surface 87 of the uncoil pawl 85. Therefore, to uncoil wire, the operator need only pivot the release lever 83 to disengage the coil pawl 84 from the square teeth 90 of the reel 78 then manually withdraw wire from the housing.

FIG. 16G shows the release lever pivoted such that the coil pawl 84 engages the square teeth 90, allowing rotation in the coil direction but preventing uncoil rotation. Because the coil pawl 84 is the reverse shape of the uncoil pawl 85, the angled surface 86 of the coil pawl faces the direction of coiling rotation and is deflected out of the way by oncoming square teeth 90. The flat edge surface 87 of the coil pawl 84 catches the square teeth to prevent uncoiling rotation. Pivoting the release lever 83 in this position allows the reel 78 to rotate automatically by the torque provided by the return spring thereby recoiling the wire. The release lever 83 has contours 94 and 95 to orient the user with which side of the release lever should be depressed to coil or uncoil wire. The uncoil contour 94 is convex, shaped outward to signify that depressing this side of the lever releases wire out of the housing. The coil contour 95 is concave, shaped inward to signify that depressing this side of the lever returns the wire into the housing.

FIG. 16H, 16I and 16J show the reel 78 of this housing embodiment having placed around its surface an annulus of pliable gripping material 76 such as silicone sponge type R10470 available from CHR Industries of New Haven, CT. The material is capable of being pierced by the end of an entering wire 21 as it initially encounters the reel 78. Once the wire 21 pierces the pliable material 76 as shown in FIG. 16H, frictional gripping force is provided as the material resiliently springs back around the puncture site to surround and frictionally engage the wire. The frictional force on the wire is sufficient to resist the pulling force on the wire as the reel 78 begins to rotate as shown in FIG. 16I. The wire is guided to the peripherally disposed gripping material by the orientation of the bore 54

the center of the reel to define a circumferential corner 82. The wire is retained within the corner 82 defined by the lip 80. The reel 79 is allowed to rotate freely as the wire is being withdrawn from the reel or upon reinsertion of the wire into the reel. As the wire is manually reinserted into the housing, it contacts the facing surface 81 of the reel 79 which directs the wire into the corner 82 and against the lip 80. The reel rotates in a plane that is angled slightly away from the axis of the wire entering the proximal storage portion 50. This orientation of the reel ensures that an incoming wire 21 contacts the facing surface 81 side of the reel 79. Engagement of the wire 21 with the lip 80 creates a moment arm around the axle 58 causing the reel 79 to rotate. As the wire is continually fed into the housing, the reel continues to rotate, collecting the wire under the lip 80. Withdrawal of the wire 21 from the housing likewise causes the reel to rotate to release the wire.

A storage receptacle to hold the proximal extension portion of the wire in its compacted form may take the form of the open wire receptacle shown in FIGS. 19, 19A and 19B. The receptacle may comprise a spool having an inverted U-shaped channel 100 formed around its perimeter to hold the wire 21 and a fixed tab 98 projecting from its side for grasping. The spool and fixed tab are rotatable about a shaft 101 extending through their center. The shaft extends into the center of a tab handle 99 that is gasped by the user to allow the spool 97 and fixed tab 99 to rotate freely to dispense the coiled wire 21. To reload wire around the spool, the fixed tab is grasped to prevent rotation and the wire is manually wound around the spool 97 into the U-shaped channel 100.

FIGS. 19C and 19D shown various means for retaining the coiled wire within the U-shaped channel 100 of the spool. FIG. 19C shows the U-shaped channel having inwardly projecting shoulders 105 extending around the perimeter of the spool 97. The shoulders restrain a pliable restraining wrap 106 within the channel, which covers and retains the wire 21 wrapped around the spool. To release the wire from the reel, the wrap

all of the wire must be withdrawn from the receptacle and the receptacle removed so that the most proximal end of the wire is exposed. The indwelling catheter then can be withdrawn over the proximal portion of the wire. Wire position within the patient is maintained by holding the uncovered part of the wire to resist the frictional force of the withdrawing catheter. After the first catheter has been completely removed from the guidewire, the next catheter can be loaded onto the proximal end of the guidewire and advanced into the patient. Again, the uncovered part of the wire is held to resist any frictional force of the advancing catheter, maintaining wire position so that the new catheter will be directed to the same treatment area in the patient's vasculature.

After the exchange, if the connection joining the proximal and distal portion of the wire is releasable, the proximal portion of the guidewire may be detached from the distal portion of the wire in the same manner as a conventional extension wire. If the connection is permanent, the physician may wish to cut off the proximal portion at the connection point for easier handling. If yet another exchange is anticipated, the physician may decide to leave the wire fully extended for the remainder of the procedure or may return the wire to the receptacle. Several embodiments of the present invention allow the physician to reload the proximal portion of the wire back to the receptacle for storage in a compact configuration until it is needed again.

From the foregoing it will be appreciated that a simpler and more effective method and apparatus for performing catheter exchanges has been presented. The guidewire and receptacle embodiments described above will allow a physician to contain the more flexible proximal extension portion of the guidewire in an easily manageable size until it is needed for an exchange. The receptacle may be grasped and used as a steering handle to guide the more rigid distal portion of the wire through the patient's vasculature to the area of treatment. When the proximal extension portion of the wire is needed for an

Claims

1. A self-contained medical guidewire and separable storage system therefor comprising, in combination:

an elongate flexible guidewire having a proximal end, a distal end and a proximal portion constructed and arranged to be reformed into a compacted configuration of substantially reduced dimensions;

a compact storage receptacle retaining the proximal portion of the guidewire in its compacted configuration, the receptacle being constructed and arranged to enable the removal of the proximal portion therefrom;

at least the proximal portion of the guidewire being formed from a material and being constructed so that upon removal from the housing, the proximal portion of the guidewire will return substantially to its elongate, non-compacted configuration.

2. A system as defined in claim 1 wherein the proximal portion of the guidewire is more flexible than the distal portion.

3. A system as defined in claim 2 wherein the proximal portion of the guidewire may be confined in a coiled configuration of a diameter as small as approximately equal to twenty times the wire diameter, yet returned to a substantially straight configuration when released.

4. A system as defined in claim 2 wherein the proximal portion and distal portions of the guidewire are fabricated from dissimilar materials.

13. A system as defined in claim 1 wherein the receptacle further comprises:

a frangible shell housing formed to contain the proximal portion of the guidewire in a compacted configuration.

14. A storage system as defined in claim 13 further comprising a release tab associated with the shell and being constructed and arranged to initiate separation of the shell from the compacted wire.

15. A system as defined in claim 1 wherein the receptacle further comprises:

a housing having an access port adapted to enable the proximal portion of the guidewire to be withdrawn from and reloaded into the housing and

the housing containing internal members constructed and arranged to cause the proximal portion of the wire to be reformed to its compacted configuration within the housing and to store the compacted wire in readiness for withdrawal from the housing .

16. A system as defined in claim 15 wherein the internal members comprises the interior of the housing having surfaces contoured to direct the proximal portion of the guidewire into a coiled configuration and to retain the wire in the coiled configuration.

17. The housing of claim 15 further comprising:

a hollow storage portion shaped to contain the proximal portion of the guidewire in a coiled configuration: and

a neck disposed between the housing and the access port, the neck having a guidewire-receptive bore oriented to guide the guidewire in a straight configuration as it exits the housing through the bore.

25. A system as defined in claim 16 wherein the internal members comprise a wire storage reel rotatably mounted within the housing.

26. A system as defined in claim 25 further comprising:

a crank arm connected to the storage reel and having a handle end protruding through the housing.

27. A system as defined in claim 25 further comprising:

means biasing the storage reel in one rotary direction for enabling the reel to wind the wire thereon.

28. A system as defined in claim 27 wherein the biasing means comprises an automatic return spring connected to and providing rotational force to the wire storage reel.

29. A system as defined in claim 28 further comprising:

a release lever having at least one pawl and being pivotally mounted to the housing and

the reel having teeth formed around its circumference that are engagable with the pawl of the release lever.

30. The housing of claim 27 further comprising:

a wire braking assembly mounted on the housing adapted to enable regulation of the rate at which the wire is drawn into the housing.

38. The guidewire of claim 31 wherein:
the overall length of the guidewire is approximately 400 centimeters.

39. The guidewire of claim 31 wherein:
the distal portion is approximately 145 centimeters long and the proximal portion is approximately 155 centimeters long.

40. A guidewire as defined in claim 31 wherein the overall length of the guidewire is approximately twice that of the catheter.

41. A compactable extension wire for connection to the proximal end of a medical guidewire and storage system therefore comprising:
an elongated flexible shaft constructed and arranged to be reformed into a compacted configuration of substantially reduced dimensions;
a compact storage receptacle adapted to contain the extension wire in its compacted configuration, the receptacle being constructed and arranged to enable the removal of the extension wire therefrom;
the extension wire being formed from a material and being constructed so that upon removal from the receptacle the extension wire will substantially return to its elongate, non-compacted configuration.

42. A combination of a medical catheter and guidewire wherein:
the guidewire has a distal end and a proximal end that is more flexible than

removing the proximal portion of the wire from the receptacle;

withdrawing the catheter out of the patient, over the distal portion of the wire while grasping the proximal extension portion of the wire to maintain the wire in the same position within the patient;

installing the second catheter over the proximal and distal portions of the wire and advancing the second catheter into the patient;

returning the proximal extension portion of the guidewire to the receptacle to be retained in a compact configuration.

45. A self-contained medical guidewire and separable storage system therefor comprising:

an elongated flexible guidewire having a proximal end, a distal end and a proximal portion constructed and arranged to be deformed into a compacted configuration of substantially reduced dimensions;

a compact frangible shell storage housing formed to contain and enclose the proximal portion of the guidewire in a compacted configuration, the housing being constructed and arranged to enable the removal of the proximal portion guidewire therefrom via a release tab associated with the shell and being constructed and arranged to initiate separation of the shell from the wire.

at least the proximal portion of the guidewire being formed from a material and being constructed so that upon removal from the housing, the proximal portion of the guidewire will substantially return to its elongate, non-compacted configuration.

46. A self-contained medical guidewire and separable storage system therefor comprising:

48. A self-contained medical guidewire and separable storage system therefor comprising:

an elongated flexible guidewire having a proximal end, a distal end and a proximal portion constructed and arranged to be deformed into a compacted configuration of substantially reduced dimensions;

a compact storage housing having internal dimensions adapted to contain the proximal portion of the guidewire in its compacted configuration, the housing being constructed and arranged to enable the removal of the proximal portion of the guidewire therefrom and having a wire braking assembly to slow and stop movement of the wire into or out of the housing;

at least the proximal portion of the guidewire being formed from a material and being constructed so that upon removal from the housing, the proximal portion of the guidewire will substantially return to its elongate, non-compacted configuration.

49. A self-contained medical guidewire and separable storage system therefor comprising:

an elongated flexible guidewire having a proximal end, a distal end and a proximal portion constructed and arranged to be deformed into a compacted configuration of substantially reduced dimensions;

an open compact storage receptacle adapted to retain the proximal portion of the guidewire in its compacted configuration, the receptacle being constructed and arranged to enable the removal of the proximal portion of the guidewire therefrom and return thereto;

at least the proximal portion of the guidewire being formed from a material and being constructed so that upon removal from the housing, the proximal portion of the guidewire will substantially return to its elongate, non-compacted configuration.

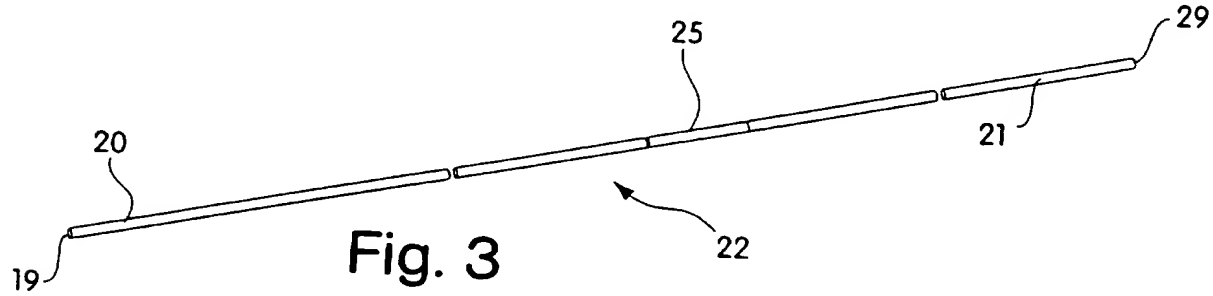


Fig. 3

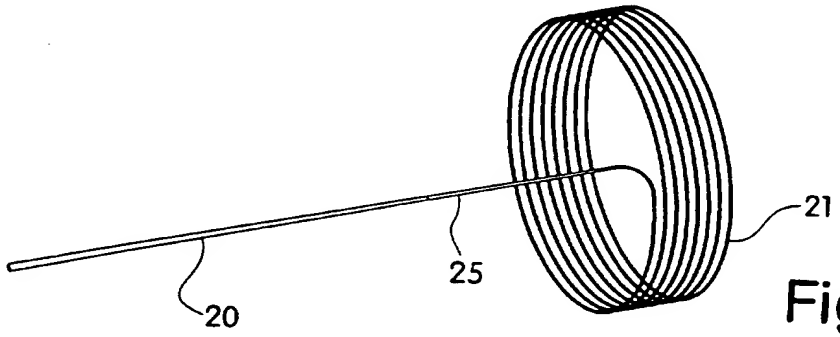
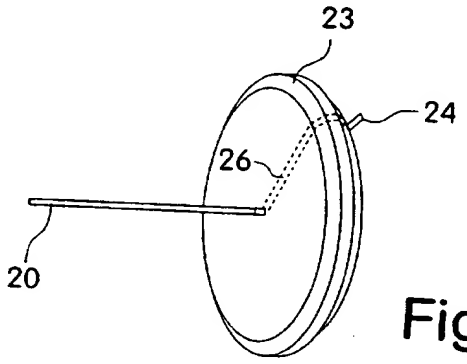


Fig. 4



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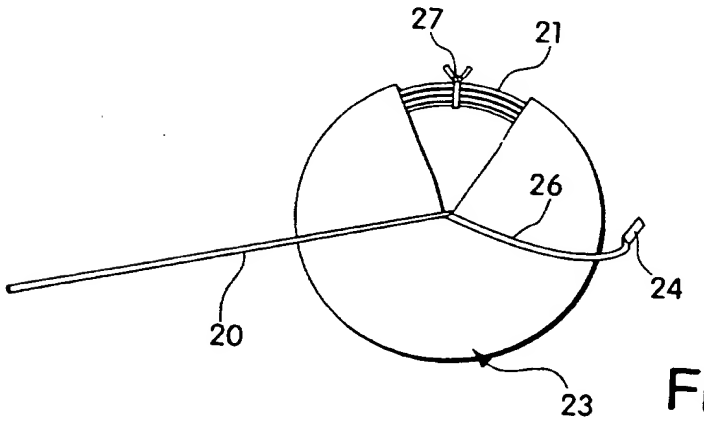

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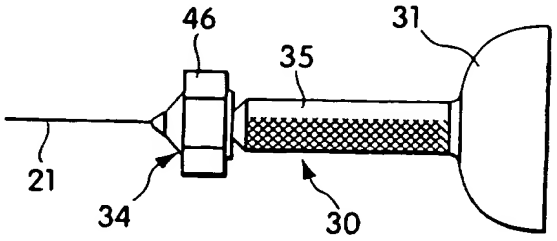

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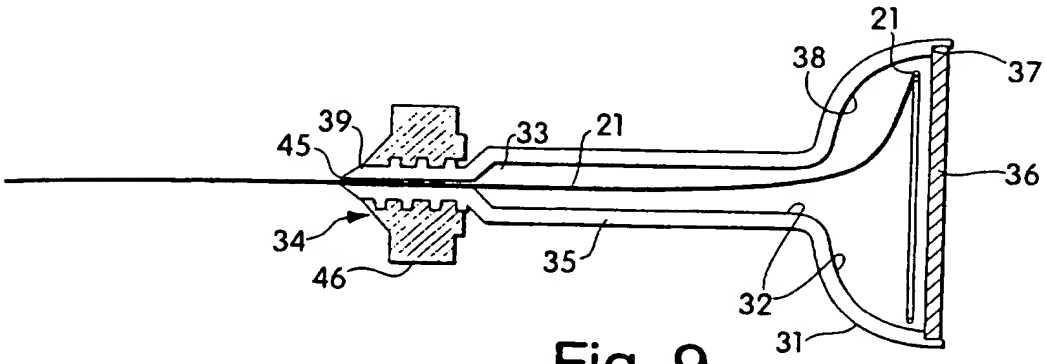

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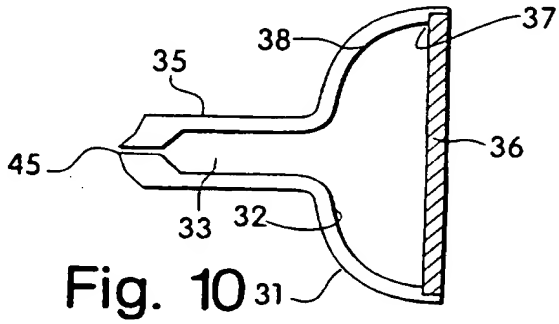
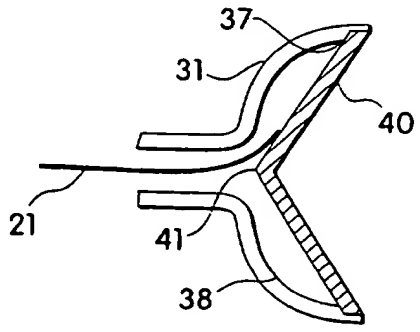


Fig. 10



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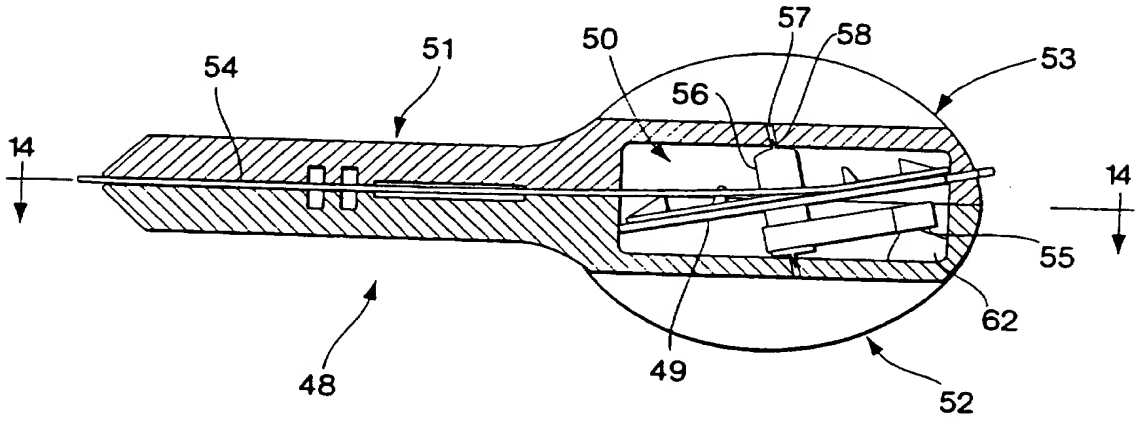

Fig. 13

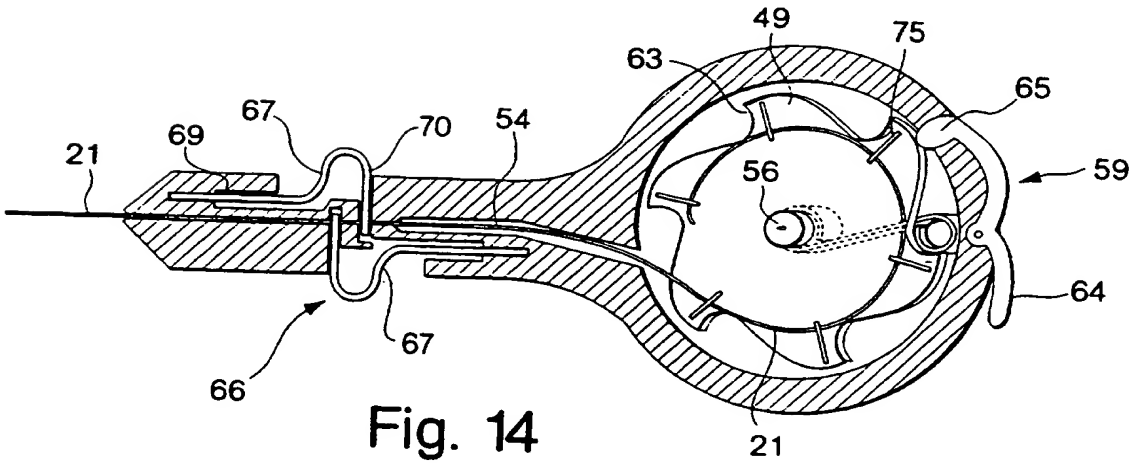

Fig. 14

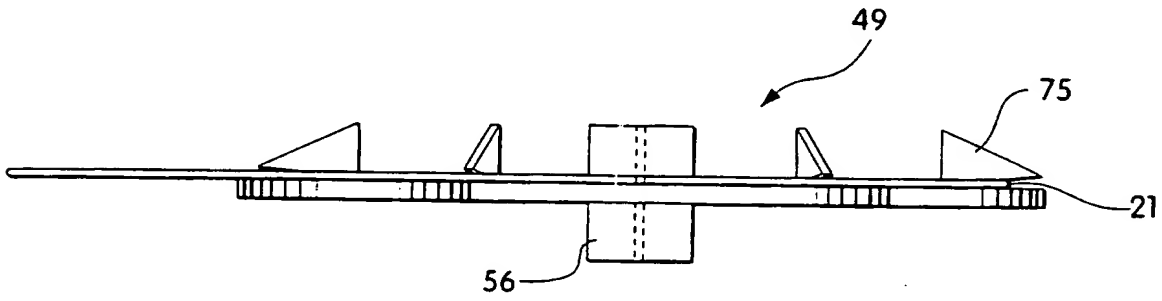

Fig. 15D

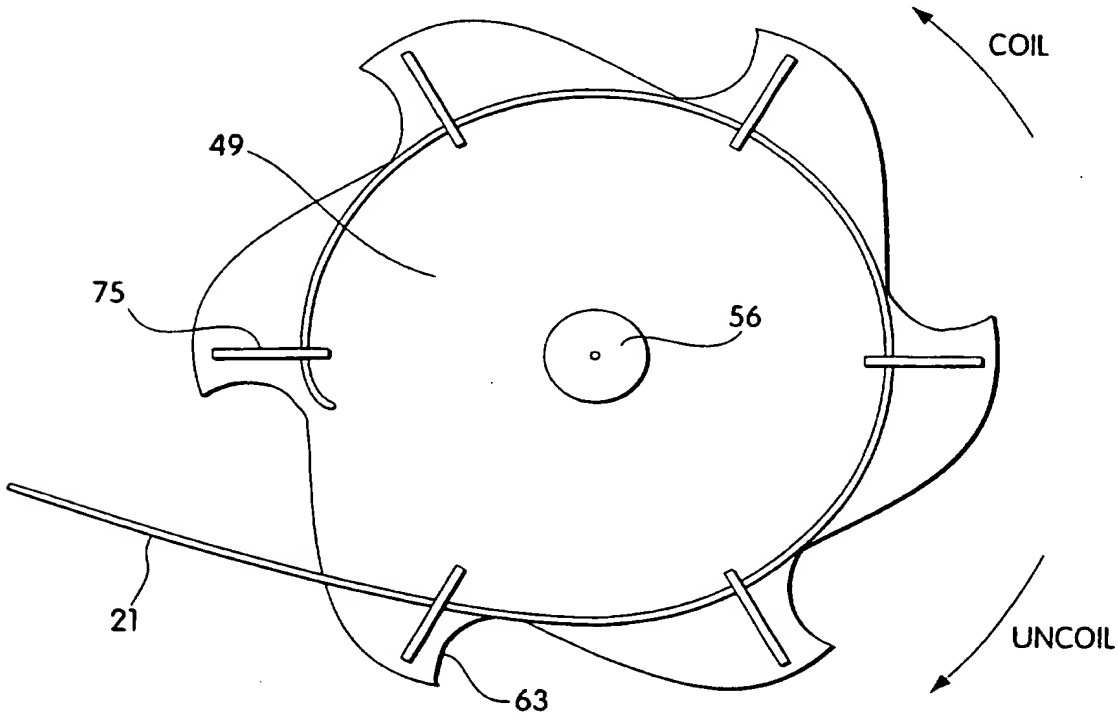

Fig. 15E

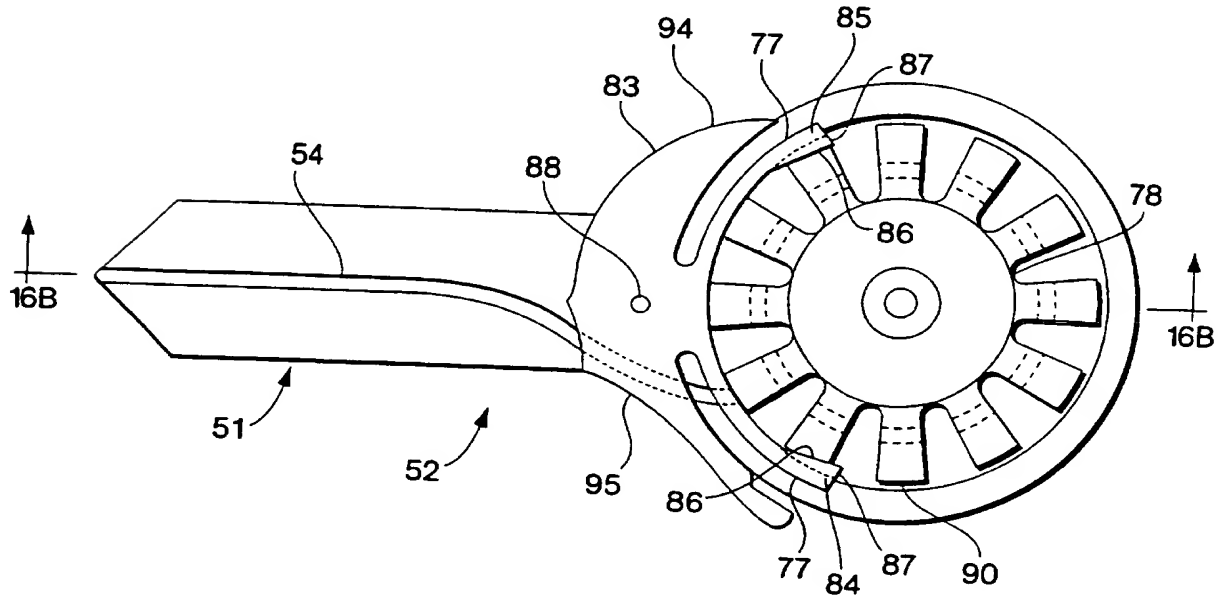

Fig. 16A

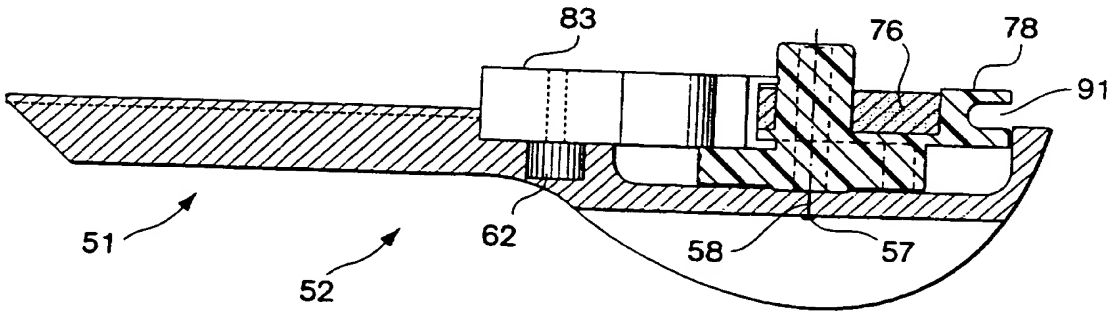

Fig. 16B

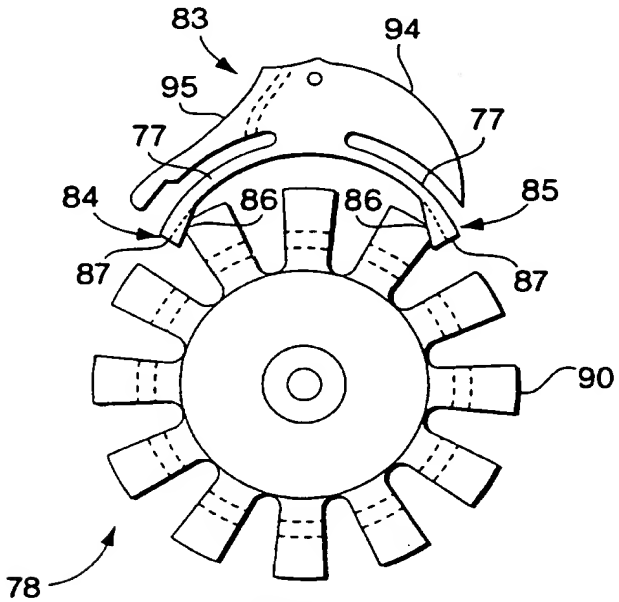

Fig. 16E

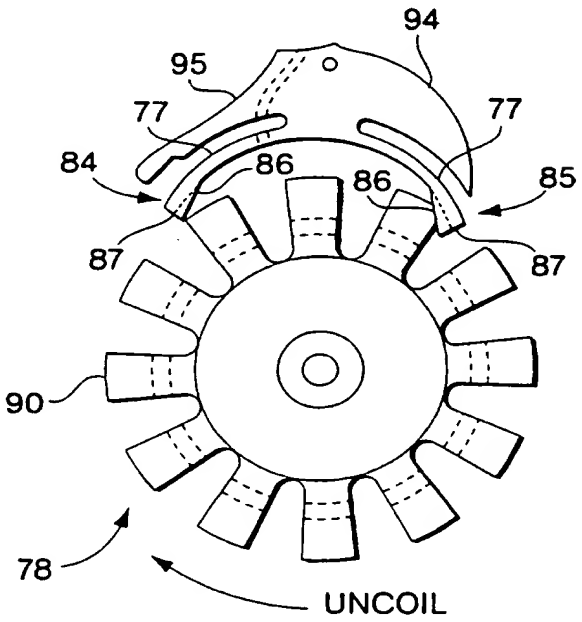

Fig. 16F

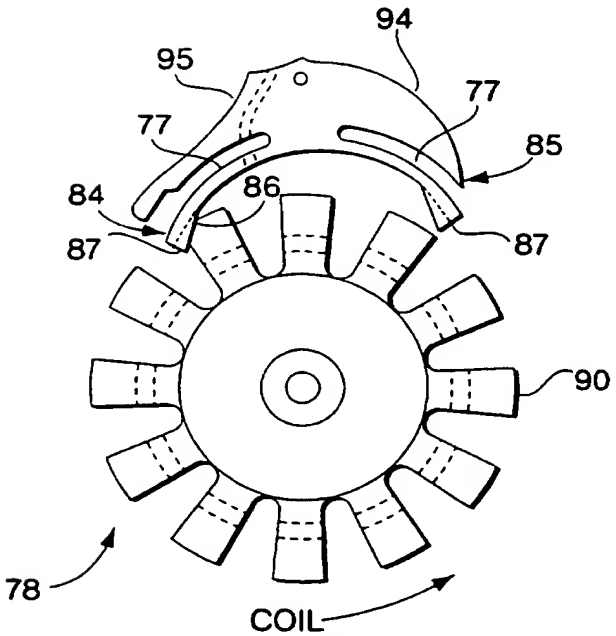

Fig. 16G

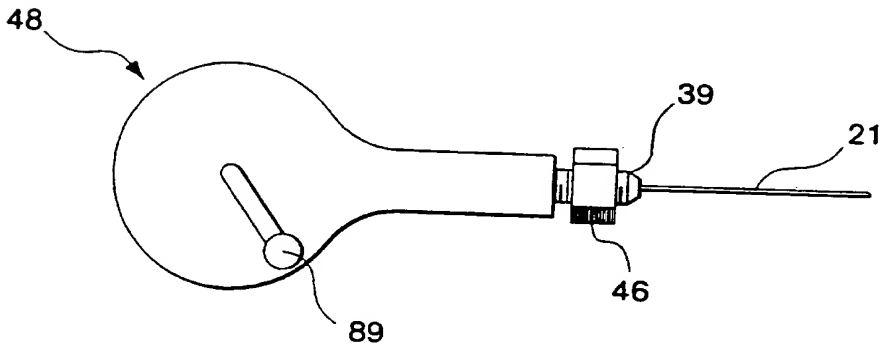

Fig. 17

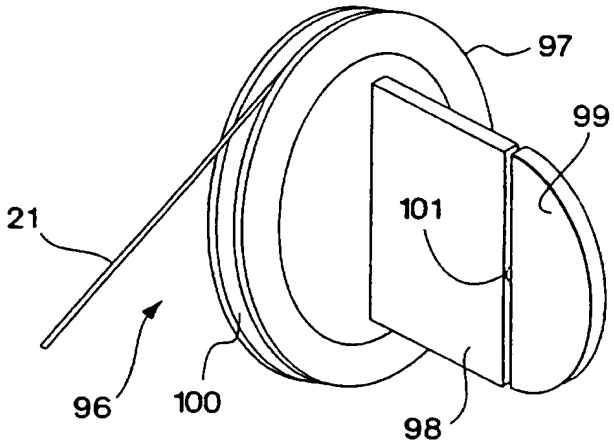

Fig. 19

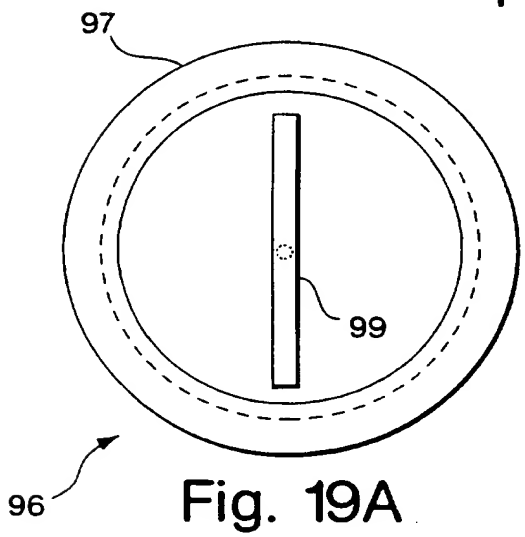

Fig. 19A

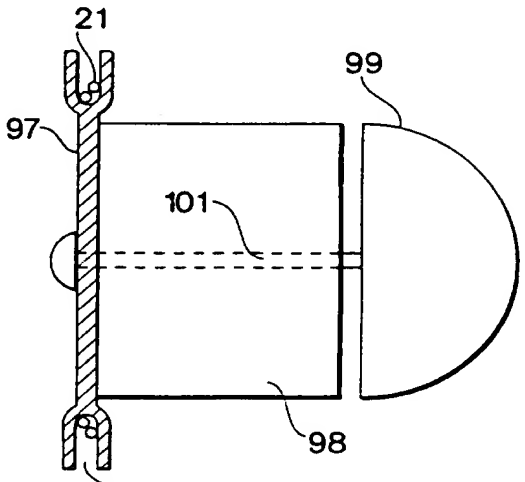

Fig. 19B

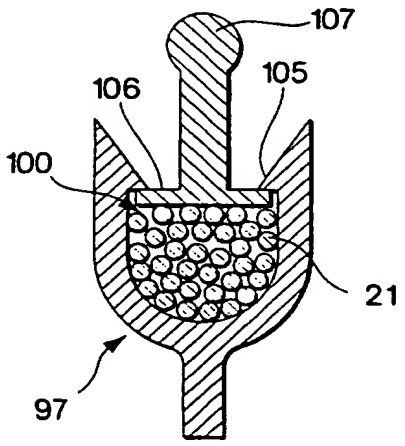

Fig. 19C

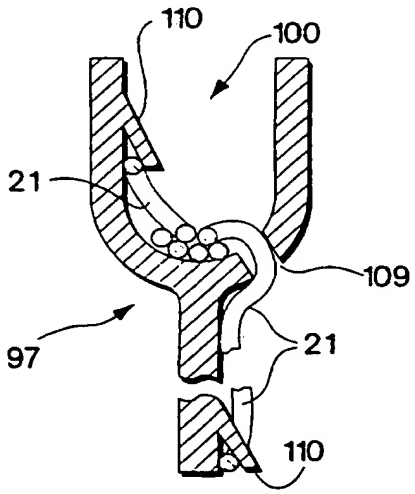

Fig. 19D

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 96/15411

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